

Remarks

Claims 1, 4 and 5; 1-4 and 8; 1, 3 and 6 ; 1, 7 and 8 and 1, 3, 5 and 9 stand rejected under 35 U.S.C. 102(b) as being anticipated by Edgen et al. ;Davis et al. ; Lippmann et al.; Straub et al. and Bar-Shalom et al. These rejections are traversed. The claimed invention relates to a solid powderous excipient consisting of two components, a polymeric carrier and a surfactant with solubilizing properties which at 20°C is liquid or semi-solid. Such surfactants are due to their wax-like properties difficult to handle and can cause problems especially in the case of direct compression of tablets. By making a powderous excipient in which the liquid or semi-solid surfactant is absorbed to the polymeric carrier, such surfactant are much easier to handle and can be easily processed into pharmaceutical formulations.

This is not disclosed by the prior art cited by the examiner. Edgen et al. ('346) do not disclose a powderous excipient consisting of two components as described above. This document relates to specific coating compositions for drug delivery forms to provide for a single unit coat around the active ingredient. Davis et al. ('158) which is cited for disclosing spray-drying of a composition relates to the spray-drying of mixtures containing an active ingredient (bisacodyl). Producing a solid mixture of two excipients is not mentioned. Lippmann et al. ('315) relates to gelatine capsules containing a mixture of a microencapsulated potassium salt and a surfactant or a mixture of surfactants. The making or use of a powdererous excipient consisting of the said two components is not disclosed. Straub et al. ('698) relates to the manufacturing of microcapsules containing a fluorinated

gas useful in diagnostics. Such gas-filled microcapsules can be obtained by spray-drying. However, such gas-filled such gas-filled microcapsules cannot be identical to the claimed powderous excipient which is not gas-filled. Bar-Shalom et al. ('560) discloses drug delivery devices based on a matrix of a crystalline polymer and a surface active agent. It is also mentioned that the components can be mixed by melt-extrusio. The mixtures are then either mixed with an active ingredient or processed in such a way by extrusion or injection of the melt, that matrix layers wlth or without active ingdredients are formed. It should be noted that the manufacturing of a solid excipient, which is for instance prepared by melt extrusion and then isolated in powderous form and subsequently processed into a formulation is not disclosed. Since no single reference discloses each and every element of the claimed composition, there is no adequate basis for a holding of anticipation (see In re Marshall (CCPA 1978) 198 U.S.P.Q. 344).

Claims 1-9 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Edgren et al., Davis et al., and Lippmann et al. all in view of Straub et al. and Bar-Shalom et al. This rejection is traversed. In this regard, it should be noted that the prior art teachings neither suggest the problem of processing liquid or semi-solid surfactants nor the possible solution of such a problem by pre-fabricating a powderous excipient wherein the surfactant is absorbed to a polymeric carrier. Therefore, a person of ordinary skill is not the instantly claimed invention by any combination of the cited prior art.

In view of the foregoing remarks, the applicants respectfully urge that the invention claimed herein is patentable and a notice of allowance is solicited.

BERNDL et al.

Serial No 09/937,313

Please find attached a check for \$400.00 for a two month extension of time fee.

To the extent necessary, applicant(s) petition for an Extension of Time under 37 CFR 1.136. Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,
KEIL & WEINKAUF



Henry R. Jiles
Reg. No. 32,677

1101 Connecticut Ave., N.W.
Washington, D.C. 20036
(202)659-0100
HRJ/mks